



DEPARTMENT OF HEALTH & HUMAN SERVICES

CPH: H7505L
Public Health Service

Duffy

Food and Drug Administration
Rockville MD 20857

OCT - 5 1990

Mr. Frederick H. von Unwerth
Kilpatrick and Cody
Suite 500
2501 M Street, NW
Washington, DC 20037

Dear Mr. von Unwerth:

In your July 10, 1989, letter to Edwin F. Tinsworth of the Environmental Protection Agency (EPA), Office of Pesticides Programs, regarding modification of the Consumer Information Sheet for Hickson Corporation's Wolmanized Chromated-Copper-Arsenate (CCA) treated wood, you wrote that The Food and Drug Administration (FDA) approved Hickson Corporation's product for use in the construction of silage and feed bunkers, and water troughs for food producing animals. This response addresses your assertion that FDA has approved the use of Wolmanized-treated wood in the manner discussed in your letter

Your assertion about FDA approval is incorrect. My letter of February 23, 1989, was not an approval under the Federal Food, Drug, and Cosmetic Act (FFDCA) or FDA's regulations. Indeed, my letter was not even a statement binding or otherwise obligating or committing FDA to the views expressed in 21 CFR Section 10.85(k). Rather, my letter simply stated my best judgment at the time and reflected my opinion that, in the exercise of its enforcement discretion, see *Heckler v. Chaney*, 470 U.S. 821 (1985), FDA would not object to the above use of Wolmanized wood.

In any event, as stated in the last paragraph of the February 23 letter we reserved the authority to withdraw the letter based on questions of safe use. After discussing this matter with EPA, we have come to the conclusion that withdrawal of the February 23 letter is necessary.

Based on the data provided by Hickson we believe that the use of Wolmanized wood discussed in your letter is likely to result in residues of arsenic (the active ingredient in Wolmanized wood) in feed and water that comes in contact with the wood. The meat from animals consuming the contaminated feed and water is also likely to contain arsenic residues. Such residues would result in the arsenic being a food additive requiring FDA approval.

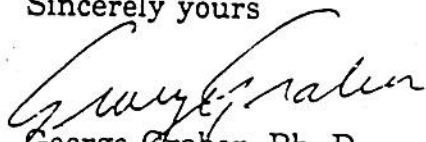
As you may be aware, arsenic is considered a human carcinogen. EPA has classified arsenic as "Group-A" -- Human Carcinogen, the category reserved for agents for which there is sufficient evidence to support a causal association between exposure and cancer. Therefore,

particularly/especially stringent pre-approval requirements must be met before FDA can approve the use of arsenic-treated wood in an animal food contact situation. Use of Wolmanized wood (or any wood treated with inorganic arsenicals) for use in animal food contact situations requires FDA approval in the form of a food additive regulation, based on a food additive petition, submitted by Hickson Corporation, in accordance with section 409 of the FFDCA (21 U.S.C. Section 348) and 21 CFR Part 571. Such a petition must satisfy requirements of the DES Proviso as well as the Safety Clause in section 409.

By this correspondence we are withdrawing the letter of February 23, and notifying Hickson Corporation that it must cease marketing of CCA-treated wood for use in the construction of silos, feed bunkers, and water troughs for animals.

We request that within 30 days of the date of this letter you inform us what actions have been taken by your client to stop the promotion and marketing of Wolmanized wood for use in the construction of silos, feed bunkers, and water troughs for animal feed. Further use of Wolmanized CCA-treated wood for the holding of animal feed and drinking water requires the submission of a food additive petition. I may be reached by telephone on 301-443-3390.

Sincerely yours



George Graber, Ph. D.
Director

Division of Animal Feeds
Center for Veterinary Medicine